

WHAT IS CLAIMED IS:

1. A method of using zonisamide as an adjunctive therapy for partial seizures to improve the safety of such therapy comprising:

 providing a patient with a therapeutically effective amount of zonisamide,

 and

 informing the patient or the patient's guardian during the course of zonisamide therapy that hypercalcemia, renal insufficiency, fatigue, anemia, bone pain, spontaneous fractures, increased frequency or duration of infection, or abnormal urine color or odor are symptoms of monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or multiple myeloma (MM) that require prompt medical evaluation if such symptoms are experienced by the patient.
2. The method of claim 1 wherein the therapeutically effective amount of zonisamide is from 25 mg to 600 mg.
3. The method of claim 1 wherein the therapeutically effective amount of zonisamide is provided in unit dose form.
4. The method of claim 1 wherein the therapeutically effective amount of zonisamide is provided in a unit dose form and in multiple doses to provide for a course of therapy.
5. The method of claim 4, wherein the unit dose is from 25 mg to 200 mg.
6. A method of using zonisamide as an adjunctive therapy for partial seizures to improve the health of a patient receiving such therapy comprising:

providing a patient with a therapeutically effective amount of zonisamide,
and

informing the patient or the patient's guardian during the course of such therapy that hypercalcemia, renal insufficiency, fatigue, anemia, bone pain, spontaneous fractures, increased frequency or duration of infection, or abnormal urine color or odor are symptoms of monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or multiple myeloma (MM) that require prompt medical evaluation if such symptoms are experienced by the patient.

7. The method of claim 6 wherein the therapeutically effective amount of zonisamide is from 25 mg to 600 mg.

8. The method of claim 6 wherein the therapeutically effective amount of zonisamide is provided in unit dose form.

9. The method of claim 6 wherein the therapeutically effective amount of zonisamide is provided in a unit dose form and in multiple doses to provide for a course of therapy.

10. The method of claim 9, wherein the unit dose is from 25 mg to 200 mg.

11. A method of using zonisamide as an adjunctive therapy for partial seizures to reduce the risk of monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or multiple myeloma (MM) in a patient receiving such therapy comprising:

providing the patient with a therapeutically effective amount of zonisamide,
and

informing the patient or the patient's guardian during the course of
zonisamide therapy that hypercalcemia, renal insufficiency, fatigue, anemia, bone
pain, spontaneous fractures, increased frequency or duration of infection, or
abnormal urine color or odor are symptoms of monoclonal gammopathy of
undetermined significance (MGUS), smoldering multiple myeloma (SMM), or
multiple myeloma (MM) that require prompt medical evaluation if such symptoms
are experienced by the patient.

12. The method of claim 11 wherein the therapeutically effective
amount of zonisamide is from 25 mg to 600 mg.

13. The method of claim 11 wherein the therapeutically effective
amount of zonisamide is provided in unit dose form.

14. The method of claim 11 wherein the therapeutically effective
amount of zonisamide is provided in a unit dose form and in multiple doses to
provide for a course of therapy.

15. The method of claim 14, wherein the unit dose is from 25 mg to 200
mg.

16. A method of using zonisamide as an adjunctive therapy for partial
seizures comprising:

enhancing the safety profile of zonisamide by informing a prescribing
physician that monoclonal gammopathy of undetermined significance (MGUS),

smoldering multiple myeloma (SMM), or multiple myeloma (MM) may result from zonisamide therapy;

advising the physician to monitor a patient who is prescribed zonisamide as an adjunctive therapy for partial seizures for one or more symptoms chosen from the group of hypercalcemia, renal insufficiency, fatigue, anemia, bone pain, spontaneous fractures, increased frequency or duration of infection, or abnormal urine color or odor, and when such a symptom is observed,

recommending that a laboratory test for paraproteinemia, M-spike protein in serum, Bence-Jones protein in urine, or depression of normal immunoglobulin levels be performed, and

if the test reveals an abnormal result for that patient, recommending that the physician consider removing, reducing, or tapering off zonisamide dosing in the patient while initiating appropriate supportive therapy.

17. A method of using zonisamide as an adjunctive therapy for partial seizures comprising:

improving patient outcome by informing an emergency medical worker that a patient who is receiving zonisamide as an adjunctive therapy for partial seizures and exhibits hypercalcemia, renal insufficiency, fatigue, anemia, bone pain, spontaneous fractures, increased frequency or duration of infection, or abnormal urine color or odor, may be suffering from monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or multiple myeloma (MM); and when such a symptom is observed,

recommending that an appropriate laboratory test for paraproteinemia, M-spike protein in serum, Bence-Jones protein in urine, or depression of normal immunoglobulin levels be performed,

and if the result of that test is abnormal for that patient, recommending that the worker initiate appropriate supportive therapy and discontinue or reduce zonisamide dosing in the patient.

18. The method of any of claim 17 wherein the diagnostic comprises measurement of M-spike protein in serum.

19. The method of claim 17 wherein the diagnostic comprises measurement of Bence-Jones protein in urine.

20. The method of any of claims 17 wherein the prescribed dosage of zonisamide is from 25 mg to 600 mg.

21. The method of claim 17 wherein the therapeutically effective amount of zonisamide is provided in unit dose form.

22. The method of claim 17 wherein the patient is receiving zonisamide in a therapeutically effective amount provided in a unit dose form and in multiple doses to provide for a course of therapy.

23. The method of claim 21 wherein the unit dose is from 25 mg to 200 mg.

24. A method of using zonisamide as an adjunctive therapy for partial seizures comprising:

providing packaging that includes a pharmaceutical formulation of zonisamide along with information providing a warning that zonisamide may

cause monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or multiple myeloma (MM) in some patients and that one or more symptoms chosen from the group of hypercalcemia, renal insufficiency, fatigue, anemia, bone pain, spontaneous fractures, increased frequency or duration of infection, or abnormal urine color or odor are potentially signs of monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or multiple myeloma (MM); and providing such packaging to a patient who has been prescribed zonisamide.

25. The method of claim 24 wherein the formulation contains a therapeutically effective amount of zonisamide of from 25 mg to 600 mg.

26. The method of claim 24 wherein the therapeutically effective amount of zonisamide is provided in unit dose form.

27. The method of claim 24 wherein the therapeutically effective amount of zonisamide is provided in unit dose form and in multiple doses to provide for a course of therapy.

28. The method of claim 24 wherein the unit dose is from 25 mg to 200 mg.

29. A method of using zonisamide as an adjunctive therapy for partial seizures comprising:

providing a patient with a therapeutically effective amount of zonisamide and a therapeutically effective amount of at least one other anti-epilepsy drug, and

informing the patient or the patient's guardian that hypercalcemia, renal insufficiency, fatigue, anemia, bone pain, spontaneous fractures, increased frequency or duration of infection, or abnormal urine color or odor are symptoms of monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or multiple myeloma (MM) that require prompt medical evaluation if such symptoms are experienced by the patient.

30. The method of claim 29, wherein the patient or patient's guardian is informed by reference to a package drug insert.

31. A method of administering zonisamide as an adjunctive therapy for partial seizures comprising:

providing a patient with a therapeutically effective amount of zonisamide and a therapeutically effective amount of at least one other anti-epilepsy drug; and

informing the patient or the patient's guardian that hypercalcemia, renal insufficiency, fatigue, anemia, bone pain, spontaneous fractures, increased frequency or duration of infection, or abnormal urine color or odor are symptoms of monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), or multiple myeloma (MM) that require prompt medical evaluation if such symptoms are experienced by the patient.

32. The method of claim 31, wherein the patient or patient's guardian is informed by reference to a package drug insert.

33. A method of using zonisamide as an adjunctive therapy for partial seizures comprising:

monitoring a patient who is receiving administrations of zonisamide for one or more symptoms chosen from the group of hypercalcemia, renal insufficiency, fatigue, anemia, bone pain, spontaneous fractures, increased frequency or duration of infection, or abnormal urine color or odor;

if one or more of said symptoms are observed, performing a laboratory test for paraproteinemia, M-spike protein in serum, Bence-Jones protein in urine, or depression of normal immunoglobulin levels of the patient; and

if the laboratory test indicates an abnormal result for that patient, reducing or tapering off the zonisamide dosing.

34. The method of claim 33, wherein the zonisamide dosing is increased after subsequent laboratory test are determined to be normal for that patient.